

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1073159	(X3) Date Survey Completed 07/19/2024
Name of Provider or Supplier Pathology Laboratory, Inc, The	Street Address, City, State 1810 Bertrand Drive, Lafayette, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed on July 19, 2024 at The Pathology Laboratory, INC, CLIA ID # 19D1073159. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory temperature logs and policies and interview with personnel, the laboratory failed to establish a corrective action policy for temperatures outside of the laboratory's acceptable limits. Findings: 1. Review of the laboratory's "Front of Lab Room Temp" logs from June 2024 through July 2024 revealed the room temperature exceeded the laboratory's acceptable limits of 20 - 25 degrees Celsius on the following days: - July 2, 2024 - 19.5 degrees Celsius - July 5, 2024 - 19.9 degrees Celsius - July 8, 2024 - 19.4 degrees Celsius - July 11, 2024 - 19.5 degrees Celsius 2. Review of the laboratory's policies revealed the laboratory did not include a corrective action procedure for the actions to take when temperatures exceed acceptable limits. 3. In interview on July 19, 2024 at 1:22 p.m., the Laboratory Manager confirmed the laboratory did not have a policy for corrective action as identified above.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D6171.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5779.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training

program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report), personnel records, and patient test records; as well as interview with personnel, the laboratory failed to ensure histopathology gross examinations performed by delegated testing personnel were reviewed by a Technical Supervisor within 24 hours for twenty-nine (29) of seventy (70) patients reviewed. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the following high complexity testing personnel: a) Personnel 7 b) Personnel 8 c) Personnel 9 d) Personnel 10 e) Personnel 11 f) Personnel 12 g) Personnel 13 2. In interview on July 19, 2024 at 1:30 p.m., the Laboratory Manager stated the personnel identified above performed gross examinations of histopathology specimens. 3. Further review of the CMS 209 form revealed the following personnel as Technical Supervisors: a) Personnel 1 b) Personnel 2 c) Personnel 3 d) Personnel 4 e) Personnel 5 f) Personnel 6 4. Review of patient test records from Friday, June 28, 2024 revealed the gross examinations for the following twenty-nine (29) of seventy (70) patients were not reviewed by a Technical Supervisor within 24 hours: a) AN2024-0002938 b) AN2024-0002942 c) AN2024-0002944 d) AN2024-0002951 e) AN2024-0002954 f) N2024-0004059 g) N2024-0004064 h) N2024-0004065 i) N2024-0004066 j) S2024-0004222 k) S2024-0004223 l) S2024-0004224 m) S2024-0004225 n) S2024-0004226 o) S2024-0004227 p) S2024-0004228 q) S2024-0004229 r) S2024-0004230 s) S2024-0004231 t) S2024-0004232 u) S2024-0004233 v) S2024-0004234 w) S2024-0004244 x) S2024-0004246 y) S2024-0004248 z) S2024-0004250 aa) S2024-0004252 bb) S2024-0004254 cc) S2024-0004255 5. In interview on July 19, 2024 at 1:45 p.m., the Laboratory Manager

confirmed gross examinations performed on Fridays were not always reviewed by a Technical Supervisor within 24 hours due to weekend Pathologist scheduling.